Complete Summary

GUIDELINE TITLE

Prostate cancer. Diagnosis and treatment.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Cancer. Prostate cancer: diagnosis and treatment. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 38 p. (NICE clinical guideline; no. 58).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Prostate cancer

GUIDELINE CATEGORY

Counseling
Diagnosis
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics

Internal Medicine
Nuclear Medicine
Nursing
Oncology
Pharmacology
Psychiatry
Psychology
Radiation Oncology
Surgery
Urology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To prepare a guideline for the National Health Service (NHS) in England, Wales, and Northern Ireland for the clinical management of prostate cancer, to supplement existing service guidance, coving the following aspects:

- The key diagnostic and staging procedures – excluding screening
- The main treatment modalities including hormonal therapy (covering surgical and chemical castration)
- The role of tumour specific bisphosphonates

TARGET POPULATION

Men in England, Wales, and Northern Ireland with suspected or clinically confirmed prostate cancer, specifically:

- Adults referred from primary care for investigation of possible prostate cancer, in line with the NICE clinical guidelines on referral suspected cancer (*NICE Clinical Guideline* no. 27)
- Adults with a biopsy-proven diagnosis of primary adenocarcinoma of the prostate or an agreed clinical diagnosis* when biopsy would be inappropriate

*Agreed clinical diagnosis on the basis of, for example, digital rectal examination, high prostate-specific antigen (PSA) and known metastases

The following patient groups are **not** covered by the guideline:

- Asymptomatic adults with an abnormal, age-specific PSA level and no biopsy-proven diagnosis of prostate cancer
- Patients with metastatic disease of different primary origin involving the prostate
- Children and adults with rare malignant tumours of the prostate, such as small cell carcinoma and rhabdomyosarcoma

INTERVENTIONS AND PRACTICES CONSIDERED

Counseling

1. Individualized information on prostate cancer and access to information
2. Management options
3. Involvement of family/carers
4. Psychosexual counseling

Diagnosis/Risk Assessment

1. Prostate biopsy
2. Pelvic imaging
    - Magnetic resonance imaging (MRI)
    - Computed tomography
    - Isotope bone scans
    - Positron emission tomography (not recommended routinely)
3. Risk assignment based on prostate specific antigen (PSA) level, Gleason score, and clinical stage
4. Use of Nomograms

Management/Treatment

1. Use of multidisciplinary teams
2. Management of localised prostate cancer
    - Watchful waiting
    - Active surveillance
    - Re-biopsy
    - Radical prostatectomy
    - Radical radiotherapy (conformal)
    - Brachytherapy (not recommended for high-risk localised prostate cancer)
    - Adjuvant hormonal therapy
    - Follow-up, with regular PSA measurements
3. Managing adverse effects of treatment
    - Investigation of radiation-induced enteropathy, including flexible sigmoidoscopy
    - Steroid enemas (not recommended for radiation proctopathy)
    - Training of oncologists and gastroenterologists
    - Sperm storage
    - Treatment of erectile dysfunction (phosphodiesterase type 5 [PDE5] inhibitors, vacuum devices, intraurethral inserts, penile injections, or penile prostheses)
    - Management of stress incontinence
4. Managing relapse after radical treatment

- Serial PSA levels, PSA doubling time
- Biopsy
- Isotope bone scan if metastasis is suspected (but no routine MRI before salvage radiotherapy)
- Radical radiotherapy
- Hormonal therapy
- Entry into clinical trials

5. Management of locally advance prostate cancer
    - Systemic neoadjuvant and concurrent luteinising hormone-releasing hormone agonist (LHRAa) therapy
    - Adjuvant hormonal therapy
    - Pelvic radiotherapy
    - Post-operative radiotherapy following radical prostatectomy (not recommended outside of controlled clinical trial)
    - High-intensity focused ultrasound and cryotherapy (not recommended outside of controlled clinical trials)
    - Bisphosphonates (not recommended to prevent bone metastases)
6. Management of metastatic prostate cancer
    - Bilateral orchidectomy or continuous LHRAa therapy
    - Combined androgen blockade (not recommended as first-line treatment)
    - Bicalutamide therapy
    - Intermittent androgen withdrawal
    - Management of complications of hormonal therapy, including prophylactic radiotherapy, tamoxifen, resistance exercise
    - Management of hormone-refractory prostate cancer, including use of docetaxel and dexamethasone
    - Bisphosphonates (not recommended except for pain relief refractory to other treatments)
    - Strontium-89 for painful bone metastases
    - Integration of palliative care, including systematic needs assessment

MAJOR OUTCOMES CONSIDERED

- Prognostic value of diagnostic tests (reliability, validity, and limitations)
- Symptomatic improvement
- Quality of life
- Adverse effects
- Mortality
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Cancer (NCC-C) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

At the beginning of the development phase, initial scoping searches were carried out to identify any relevant guidelines (local, national or international) produced by other groups or institutions. Additionally, stakeholder organisations were invited to submit evidence for consideration by the Guideline Development Group (GDG), provided it was relevant to the agreed list of clinical questions.

In order to answer each question the NCC-C information specialist developed a search strategy to identify relevant published evidence for both clinical and cost effectiveness. Key words and terms for the search were agreed in collaboration with the GDG. When required, the health economist searched for supplementary papers to inform detailed health economic work, for example modeling (see section on 'Incorporating Health Economic Evidence' below and in the full version of the original guideline document).

Papers that were published or accepted for publication in peer-reviewed journals were considered as evidence. Search filters, such as those to identify systematic reviews (SRs) and randomised controlled trials (RCTs) were applied to the search strategies when necessary. No language restrictions were applied to the search; however, foreign language papers were not requested or reviewed (unless of particular importance to that question).

The following databases were included in the literature search:

- The Cochrane Library
- Medline and Premedline 1950 onwards
- Excerpta Medica (Embase) 1980 onwards
- Cumulative Index to Nursing and Allied Health Literature (Cinahl) 1982 onwards
- Allied & Complementary Medicine (AMED) 1985 onwards
- British Nursing Index (BNI) 1994 onwards
- Psychinfo 1806 onwards
- Web of Science 1970 onwards. [specifically Science Citation Index Expanded (SCI-EXPANDED) and Social Sciences Citation Index (SSCI)]
- System for Information on Grey Literature In Europe (SIGLE) 1980–2005
- Biomed Central 1997 onwards
- National Research Register (NRR)
- Current Controlled Trials

From this list the information specialist sifted and removed any irrelevant material based on the title or abstract before passing to the researcher. All the remaining articles were then stored in a Reference Manager electronic library.

Searches were updated and re-run 6–8 weeks before the stakeholder consultation, thereby ensuring that the latest relevant published evidence was included in the database. Any evidence published after this date was not included. For the purposes of updating this guideline, 1 June 2007 should be considered the starting point for searching for new evidence.

Further details of the search strategies, including the methodological filters used, are provided in the evidence review (and will also appear on the accompanying CD-ROM to this guideline).

Incorporating Health Economic Evidence

In order to assess the cost-effectiveness of each priority topic, a comprehensive systematic review of the economic literature was conducted. For those clinical areas reviewed, the information specialists used a similar search strategy as used for the review of clinical evidence but with the inclusion of a health economics and quality of life filter.

Each search strategy was designed to find any applied study estimating the cost or cost effectiveness of the topic under consideration. A health economist reviewed abstracts and relevant papers were ordered for appraisal.

Published economic evidence was obtained from a variety of sources:

- Medline 1966 onwards
- Embase 1980 onwards
- NHS Economic Evaluations Database (NHS EED)
- EconLit 1969 onwards

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs) or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias

1– Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies (for example case reports, case series)

4 Expert opinion, formal consensus

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

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Critical Appraisal and Evidence Grading

Following the literature search one researcher independently scanned the titles and abstracts of every article for each question, and full publications were obtained for any studies considered relevant or where there was insufficient information from the title and abstract to make a decision.

The researcher then individually applied the inclusion/exclusion criteria to determine which studies would be relevant for inclusion and subsequent appraisal. Lists of excluded papers were generated for each question and the rationale for the exclusion was presented to the Guideline Development Group (GDG) when required.

The researcher then critically appraised the full papers. Critical appraisal checklists were compiled for each paper and one researcher undertook the critical appraisal and data extraction. The reviewer assessed the quality of eligible studies by referring to the Scottish Intercollegiate Guidelines Network (SIGN) quality checklist for systematic reviews/meta-analyses and randomised control trials (see the "Rating Scheme for the Strength of the Evidence" field). Evidence relating to clinical effectiveness was classified using this established hierarchical system. However this checklist is less appropriate for studies reporting diagnostic tests of accuracy. In the absence of a validated hierarchy for this type of test, NICE suggests levels of evidence that take into account the factors likely to affect the validity of these studies.

For all the relevant appraised studies for a particular question, data on the type of population, intervention, comparator and outcomes (PICO) was recorded in evidence tables and an accompanying evidence summary prepared for the GDG

(see evidence review). All the evidence was considered carefully by the GDG for accuracy and completeness.

All procedures were fully compliant with NICE methodology as detailed in the 'NICE guidelines manual'.

In general, no formal contact was made with authors; however, there were ad hoc occasions when this was required in order to clarify specific details.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Cancer (NCC-C) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The Guideline Development Group (GDG)

The prostate cancer GDG was recruited in line with the existing NICE protocol as set out in the 'NICE guidelines manual'. The first step was to appoint a Chair and a Lead Clinician. Advertisements were placed for both posts and candidates were informally interviewed prior to being offered the role. The NCC-C Director, GDG Chair and Lead Clinician identified a list of specialties that needed to be represented on the GDG. Requests for nominations were sent to the main stakeholder organizations and patient organizations/charities (see Appendix 8 of the full version of the original guideline). Individual GDG members were selected by the NCC-C Director, GDG Chair and Lead Clinician, based on their application forms, following nomination from their respective stakeholder organization. The guideline development process was supported by staff from the NCC-C, who undertook the clinical and health economics literature searches, reviewed and presented the evidence to the GDG, managed the process and contributed to drafting the guideline.

Guideline Development Group Meetings

Thirteen GDG meetings were held between 10 November 2005 and 28 June 2007. During each GDG meeting (either held over one or two days) clinical questions and clinical and economic evidence were reviewed, assessed and recommendations formulated. At each meeting patient/carer and service-user concerns were routinely discussed as part of a standing agenda item.

NCC-C project managers divided the GDG workload by allocating specific clinical questions, relevant to their area of clinical practice, to small sub-groups of the GDG in order to simplify and speed up the guideline development process. These groups considered the evidence, as reviewed by the researcher, and synthesized it

into draft recommendations prior to presenting it to the GDG as a whole. Each clinical question was led by a GDG member with expert knowledge of the clinical area (usually one of the healthcare professionals). The GDG subgroups often helped refine the clinical questions and the clinical definitions of treatments. They also assisted the NCC-C team in drafting the section of the guideline relevant to their specific topic.

Patient/Carer Representatives

Individuals with direct experience of prostate cancer services gave an integral user focus to the GDG and the guideline development process. The GDG included three patient/carer representatives. They contributed as full GDG members to writing the clinical questions, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guideline and bringing service-user research to the attention of the GDG.

Expert Advisers

During the development phase of the guideline the GDG identified areas where there was a requirement for expert input on particular specialist clinical questions. The clinical questions were addressed by either the production of a position paper or a formal presentation by a recognized expert who had been identified via the relevant registered stakeholder organization.

Agreeing the Recommendations

For each clinical question the GDG were presented with a summary of the clinical evidence, and where appropriate economic evidence, derived from the studies reviewed and appraised. From this information the GDG were able to derive the guideline recommendations. The link between the evidence and the view of the GDG in making each recommendation is made explicit in the accompanying qualifying statement.

Qualifying Statements

As clinical guidelines are currently formatted, there is limited scope for expressing how and why a GDG made a particular recommendation from the evidence of clinical and cost-effectiveness. To make this process more transparent to the reader, the NCC-C felt the need for an explicit, easily understood and consistent way of expressing the reasons for making each recommendation. The way they have chosen to do this is by writing a 'qualifying statement' to accompany every recommendation and will usually cover:

- The strength of evidence about benefits and harms for the intervention being considered
- The degree of consensus within the GDG
- The costs and cost-effectiveness (if formally assessed by the health economics team)

Where evidence was weak or lacking the GDG agreed the final recommendations through informal consensus. Shortly before the consultation period, eleven key

priorities and two key research recommendations were selected by the GDG for implementation and the patient algorithms were agreed (see pages xxvii-xxxiv of the full version of the original guideline document for algorithms). To avoid giving the impression that higher grade recommendations are of higher priority for implementation, NICE no longer assigns grades to recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Incorporating Health Economics Evidence

The aim of the economic input into the guideline was to inform the Guideline Development Group (GDG) of potential economic issues relating to prostate cancer. It is important to investigate whether health services are both clinically effective and cost effective, i.e., are they 'value for money'.

The health economist helped the GDG by identifying priority topics within the guideline that might benefit from economic analysis, reviewing the available economic evidence and, where necessary, conducting economic analysis. Where published economic evaluation studies were identified that addressed the economic issues for a clinical question, these are presented alongside the clinical evidence wherever possible.

Economic Modelling

In addition to the review of the relevant clinical evidence, the GDG were required to determine whether or not the cost-effectiveness of each of the individual clinical questions should be investigated. After the clinical questions were decided, the GDG agreed which topics were an 'economic priority' for modeling. These 'economic priorities' were chosen on the basis of the following criteria, in broad accordance with the 'NICE guidelines manual':

Overall Relevance of the Topic

- The number of patients affected: interventions affecting relatively large numbers of patients were given a higher economic priority than those affecting fewer patients
- The health benefits to the patient: interventions that that were considered to have a potentially significant impact on both survival and quality of life were given a higher economic priority
- The per patient cost: interventions with potentially high financial (cost/savings) implications were given high priority compared to interventions expected to have lower financial implications
- Likelihood of changing clinical practice: priority was given to topics that were considered likely to represent a significant change to existing clinical practice

Uncertainty

- High level of existing uncertainty: higher economic priority was given to clinical questions in which further economic analysis was considered likely to reduce current uncertainty over cost-effectiveness. Low priority was given to clinical questions when the current literature implied a clearly 'attractive' or 'unattractive' incremental cost-effectiveness ratio, which was regarded as generalisable to a UK healthcare setting
- Likelihood of reducing uncertainty with further analyses (feasibility issues): when there was poor evidence for the clinical effectiveness of an intervention, then there was considered to be less justification for an economic analysis to be undertaken

Once the economic priority clinical questions had been chosen, the next task was to perform a systematic review of the cost-effectiveness literature. When relevant published evidence was identified and considered to be of sufficient quality, this information was used to inform the recommendation for that specific clinical question. When no relevant cost-effectiveness evidence was identified, or when it was not considered to be of reasonable quality, consideration was given to building a de novo economic model. This decision was made by the GDG based on an assessment of the available evidence required to populate a potential economic model.

For those clinical questions where an economic model was required, the information specialist performed supplemental literature searches to obtain additional data for modeling. Assumptions and designs of the models were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

The clinical question in this guideline selected for modeling was chosen because at the time it was considered likely that the recommendations under consideration could substantially change clinical practice in the National Health Service (NHS) and have important consequences for resource use. The details of the model are presented in the evidence review and Appendix 3 of the full version of the original guideline. During the modelling process the following general principles were adhered to:

- The GDG Chair and Clinical Lead were consulted during the construction and interpretation of the model
- The model was based on the best evidence from the systematic review
- Model assumptions were reported fully and transparently
- The results were subject to thorough sensitivity analysis and limitations discussed
- Costs were calculated from a health services perspective

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft of the guideline was prepared by the National Collaborating Centre for Cancer (NCC-C) staff in partnership with the Guideline Development Group (GDG)

Chair and Lead Clinician. This was then discussed and agreed with the GDG and subsequently forwarded to the National Institute for Health and Clinical Excellence (NICE) for consultation with stakeholders.

Registered stakeholders (see Appendix 8 of the full version of the original guideline document) had one opportunity to comment on the draft guideline and this was posted on the NICE website between 31st July and 23rd September 2007. The GRP also reviewed the guideline and checked that stakeholder comments had been addressed.

Following the consultation period the GDG finalised the recommendations and the NCC-C produced the final document. This was then submitted to NICE for approval and publication on their website. The other versions of the guideline were also discussed and approved by the GDG and published at the same time.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Cancer on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Communication and Support

The recommendations on communication and patient-centered care made in the two NICE cancer service guidance documents 'Improving outcomes in urological cancers' (2002) and 'Improving supportive and palliative care for adults with cancer' (2004) should be followed throughout the patient journey.

Men with prostate cancer should be offered individualized information tailored to their own needs. This information should be given by a healthcare professional (for example, a consultant or specialist nurse) and may be supported by written and visual media (for example, slide sets or DVDs).

Men with prostate cancer should be offered advice on how to access information and support from websites (for example, UK Prostate Link – http://www.prostate-link.org.uk/), local and national cancer information services, and from cancer support groups.

Before choosing or recommending information resources for men with prostate cancer, healthcare professionals should check that their content is clear, reliable and up-to-date.

Healthcare professionals should seek feedback from men with prostate cancer and their carers to identify the highest quality information resources.

Healthcare professionals caring for men with prostate cancer should ascertain the extent to which the man wishes to be involved in decision making and ensure that he has sufficient information to do so.

A validated, up-to-date decision aid is recommended for use in all urological cancer multidisciplinary teams (MDTs). It should be offered to men with localized prostate cancer when making treatment decisions, by healthcare professionals trained in its use. (Note: A decision aid for men with localised prostate cancer is in development in the UK by the Urology Informed Decision Making Steering Group [publication expected 2008]).Â

Healthcare professionals should discuss all relevant management options recommended in this guideline with men with prostate cancer and their partners or carers, irrespective of whether they are available through local services.

Healthcare professionals should ensure that mechanisms are in place to allow men with prostate cancer and their primary care providers to gain access to specialist services throughout the course of their disease.

Healthcare professionals should adequately inform men with prostate cancer and their partners or carers about the effects of prostate cancer and the treatment options on their sexual function, physical appearance, continence and other aspects of masculinity. Healthcare professionals should support men and their partners or carers in making treatment decisions, taking into account the effects on quality of life as well as survival.

Healthcare professionals should offer men with prostate cancer and their partners or carers the opportunity to talk to a healthcare professional experienced in dealing with psychosexual issues at any stage of the illness and its treatment.

Diagnosis and Staging of Prostate Cancer

Men who are diagnosed with prostate cancer usually present in primary care with no clear symptoms of the disease. This section assumes that men have had a digital rectal examination (DRE) and usually a prostate specific antigen (PSA) test in the primary care setting, as set out in 'Referral guidelines for suspected cancer'. (See the NGC summary of the NICE guideline Referral guidelines for suspected cancer in adults and children.)

Biopsy

The aim of prostate biopsy is to detect prostate cancers with the potential for causing harm rather than detecting each and every cancer. Men with clinically insignificant prostate cancers that are unlikely to cause symptoms or affect life expectancy may not benefit from knowing that they have the disease. Indeed, the detection of clinically insignificant prostate cancer should be regarded as an under-recognized adverse effect of biopsy.

To help men decide whether to have a prostate biopsy, healthcare professionals should discuss with them their PSA level, DRE findings (including an estimate of prostate size) and comorbidities, together with their risk factors (including increasing age and black African or black Caribbean ethnicity) and any history of a previous negative prostate biopsy. The serum PSA level alone should not automatically lead to a prostate biopsy.

Men and their partners or carers should be given information, support and adequate time to decide whether or not they wish to undergo prostate biopsy. The information should include an explanation of the risks (including the increased chance of having to live with the diagnosis of clinically insignificant prostate cancer) and benefits of prostate biopsy.

If the clinical suspicion of prostate cancer is high, because of a high PSA value and evidence of bone metastases (identified by a positive isotope bone scan or sclerotic metastases on plain radiographs), prostate biopsy for histological confirmation should not be performed, unless this is required as part of a clinical trial.

Healthcare professionals should carry out prostate biopsy following the procedure recommended in 'Undertaking a transrectal ultrasound guided biopsy of the prostate' (Prostate Cancer Risk Management Program, 2006, available from http://www.cancerscreening.nhs.uk/prostate/pcrmp01.pdf).

The results of all prostate biopsies should be reviewed by a urological cancer MDT. Men should only be re-biopsied following a negative biopsy after an MDT review of the risk characteristics including life expectancy, PSA, DRE and prostate volume.

Men should decide whether or not to have a re-biopsy following a negative biopsy, having had the risks and benefits explained to them.

Imaging

The clinical presentation and the treatment intent influence the decision about when and how to image an individual. Men with localised prostate cancer are stratified into risk groups according to their risk of recurrence (see table below).

Table: Risk Stratification for Men with Localized Prostate Cancer

Â	**PSA**	Â	**Gleason Score**	Â	**Clinical Stage**
Low risk	<10 ng/mL	**and**	=6	**and**	T1-T2a
Intermediate risk	10-20 ng/mL	**or**	7	**or**	T2b-T2c
High risk	>20 ng/mL	**or**	8-10	**or**	T3-T4*

*Clinical stage T3-T4 represents locally advanced disease.

Healthcare professionals should determine the provisional treatment intent (radical or non-radical) before decisions on imaging are made.

Imaging is not routinely recommended for men in whom no radical treatment is intended.

Computerized tomography (CT) of the pelvis is not recommended for men with low- or intermediate-risk localized prostate cancer (see table above).

Men with high-risk localised (see table above) and locally advanced prostate cancer who are being considered for radical treatment should have pelvic imaging with either magnetic resonance imaging (MRI), or CT if MRI is contraindicated.

Magnetic resonance spectroscopy is not recommended for men with prostate cancer except in the context of a clinical trial.

Isotope bone scans are not routinely recommended for men with low-risk localised prostate cancer.

Isotope bone scans should be performed when hormonal therapy is being deferred through watchful waiting in asymptomatic men who are at high risk of developing bone complications.

Positron emission tomography imaging for prostate cancer is not recommended in routine clinical practice.

Nomograms

Nomograms may be used by healthcare professionals in partnership with men with prostate cancer to:

- Aid decision making
- Help predict biopsy results
- Help predict pathological stage
- Help predict risk of treatment failure

When nomograms are used, healthcare professionals should clearly explain the reliability, validity and limitations of the prediction.

Localised Prostate Cancer

Men with high-risk localized prostate cancer (see table above) may be managed as set out in section for locally advanced prostate cancer.

Watchful Waiting and Active Surveillance

Urological cancer MDTs should assign a risk category (see table above) to all newly diagnosed men with localized prostate cancer.

Men with localized prostate cancer who have chosen a watchful waiting regimen and who have evidence of significant disease progression (that is, rapidly rising PSA level or bone pain) should be reviewed by a member of the urological cancer MDT.

Men with low-risk localized prostate cancer (see table above) who are considered suitable for radical treatment should first be offered active surveillance.

Active surveillance is particularly suitable for a subgroup of men with low-risk localised prostate cancer who have clinical stage T1c, a Gleason score of 3+3, a

PSA density of <0.15 ng/mL/mL and who have cancer in less than 50% of their total number of biopsy cores with <10 mm of any core involved.

Active surveillance should be discussed as an option with men who have intermediate-risk localised prostate cancer (see table above).

Active surveillance is not recommended for men with high-risk localised prostate cancer.

To reduce the sampling error associated with prostate biopsy, men who are candidates for active surveillance should have at least 10 biopsy cores taken.

Active surveillance should include at least one re-biopsy and may be performed in accordance with the ProSTART (Phase III randomized study of active surveillance versus radical treatment in patients with favorable-risk prostate cancer. [http://www.cancer.gov/clinicaltrials/CAN-NCIC-CTG-PR11]) protocol.

Men with localised prostate cancer who have chosen an active surveillance regimen and who have evidence of disease progression (that is, a rise in PSA level or adverse findings on biopsy) should be offered radical treatment.

The decision to proceed from an active surveillance regimen to radical treatment should be made in the light of the individual man's personal preferences, comorbidities and life expectancy.

Radical Treatment

Healthcare professionals should offer radical prostatectomy or radical radiotherapy (conformal) to men with intermediate-risk localised prostate cancer.

Healthcare professionals should offer radical prostatectomy or radical radiotherapy (conformal) to men with high-risk localised prostate cancer when there is a realistic prospect of long-term disease control.

Brachytherapy is not recommended for men with high-risk localised prostate cancer.

Clinical oncologists should use conformal radiotherapy for men with localised prostate cancer (this may also apply to some men with locally advanced prostate cancer) receiving radical external beam radiotherapy.

Men undergoing radical external beam radiotherapy for localised prostate cancer (this may also apply to some men with locally advanced prostate cancer) should receive a minimum dose of 74 Gy to the prostate at no more than 2 Gy per fraction.

Adjuvant hormonal therapy is recommended for a minimum of 2 years in men receiving radical radiotherapy for localised prostate cancer who have a Gleason score of =8.

High-intensity focused ultrasound and cryotherapy are not recommended for men with localised prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions.*

*NICE interventional procedures guidance 118,119 and 145 evaluated the safety and efficacy of cryotherapy and high-intensity focused ultrasound for the treatment of prostate cancer. NICE clinical guidelines provide guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS. As there was a lack of evidence on quality of life benefits and long-term survival these interventions are not recommended in this guideline.

Follow-up

Healthcare professionals should discuss the purpose, duration, frequency and location of follow-up with each man with localised prostate cancer (this may also apply to some men with locally advanced prostate cancer), and if he wishes, his partner or carers.

Men with prostate cancer should be clearly advised about potential longer term adverse effects of treatment and when and how to report them.

Men with prostate cancer who have chosen a watchful waiting regimen with no curative intent should normally be followed up in primary care in accordance with protocols agreed by the local urological cancer MDT and the relevant primary care organisation(s). Their PSA should be measured at least once a year.

PSA levels for all men with prostate cancer who are having radical treatment should be checked at the earliest 6 weeks following treatment, at least every 6 months for the first 2 years and then at least once a year thereafter.

Routine DRE is not recommended in men with localised prostate cancer while the PSA remains at baseline levels.

After at least 2 years, men with a stable PSA who have had no significant treatment complications, should be offered follow-up outside hospital (for example, in primary care) by telephone or secure electronic communications, unless they are taking part in a clinical trial that requires formal clinic-based follow-up. Direct access to the urological cancer MDT should be offered and explained.

Managing Adverse Effects of Treatment

Given the range of treatment modalities and their serious side effects, men with prostate cancer who are candidates for radical treatment should have the opportunity to discuss their treatment options with a specialist surgical oncologist and a specialist clinical oncologist.

Men presenting with symptoms consistent with radiation-induced enteropathy should be fully investigated (including using flexible sigmoidoscopy) to exclude inflammatory bowel disease or malignancy of the large bowel and to ascertain the nature of the radiation injury. Particular caution should be taken with anterior wall rectal biopsy following brachytherapy because of the risk of fistulation.

Men treated with radical radiotherapy for prostate cancer should be offered flexible sigmoidoscopy every 5 years.

Steroid enemas should not be used for treating men with radiation proctopathy.

The nature and treatment of radiation-induced injury to the gastrointestinal tract should be included in the training programmes for oncologists and gastroenterologists.

Prior to treatment, men and their partners should be warned that treatment for prostate cancer will result in an alteration of sexual experience, and may result in loss of sexual function.

Men and their partners should be warned about the potential loss of ejaculation and fertility associated with treatment for prostate cancer. Sperm storage should be offered.

Healthcare professionals should ensure that men and their partners have early and ongoing access to specialist erectile dysfunction services.

Men with prostate cancer who experience loss of erectile function should be offered phosphodiesterase type 5 (PDE5) inhibitors to improve their chance of spontaneous erections.

If PDE5 inhibitors fail to restore erectile function or are contraindicated, men should be offered vacuum devices, intraurethral inserts or penile injections, or penile prostheses as an alternative.

Men experiencing troublesome urinary symptoms before treatment should be offered a urological assessment.

Men undergoing treatment for prostate cancer should be warned of the likely effects of the treatment on their urinary function.

Healthcare professionals should ensure that men with troublesome urinary symptoms after treatment have access to specialist continence services for assessment, diagnosis and conservative treatment. This may include coping strategies, along with pelvic floor muscle re-education, bladder retraining and pharmacotherapy.

Healthcare professionals should refer men with intractable stress incontinence to a specialist surgeon for consideration of an artificial urinary sphincter.

The injection of bulking agents into the distal urinary sphincter is not recommended to treat stress incontinence.

Managing Relapse after Radical Treatment

Analyse serial PSA levels after radical treatment using the same assay technique.

Biopsy of the prostatic bed should not be performed in men with prostate cancer who have had a radical prostatectomy.

Biopsy of the prostate after radiotherapy should only be performed in men with prostate cancer who are being considered for local salvage therapy in the context of a clinical trial.

For men with evidence of biochemical relapse following radical treatment and who are considering radical salvage therapy:

- Routine MRI scanning should not be performed prior to salvage radiotherapy in men with prostate cancer.
- An isotope bone scan should be performed if symptoms or PSA trends are suggestive of metastases.

Biochemical relapse (a rising PSA) alone should not necessarily prompt an immediate change in treatment.

Biochemical relapse should trigger an estimate of PSA doubling time, based on a minimum of 3 measurements over at least a 6 month period.

Men with biochemical relapse after radical prostatectomy, with no known metastases, should be offered radical radiotherapy to the prostatic bed.

Men with biochemical relapse should be considered for entry to appropriate clinical trials (for example, RADICALS [or radiotherapy and androgen deprivation in combination after local surgery]).

Hormonal therapy is not routinely recommended for men with prostate cancer who have a biochemical relapse unless they have:

- Symptomatic local disease progression
- Any proven metastases
- A PSA doubling time of <3 months

Locally Advanced Prostate Cancer

There is no universally accepted definition of locally advanced prostate cancer. It covers a spectrum of disease from a tumor that has spread through the capsule of the prostate (T3a) to large T4 cancers that may be invading the bladder or rectum or have spread to pelvic lymph nodes.

Systemic Treatment

Neoadjuvant and concurrent luteinising hormone-releasing hormone agonist (LHRHa) therapy is recommended for 3 to 6 months in men receiving radical radiotherapy for locally advanced prostate cancer.

Adjuvant hormonal therapy in addition to radical prostatectomy is not recommended, even in men with margin-positive disease, other than in the context of a clinical trial.

Adjuvant hormonal therapy is recommended for a minimum of 2 years in men receiving radical radiotherapy for locally advanced prostate cancer who have a Gleason score of = 8.

Bisphosphonates should not be used for the prevention of bone metastases in men with prostate cancer.

Radiotherapy

Clinical oncologists should consider pelvic radiotherapy in men with locally advanced prostate cancer who have a >15% risk of pelvic lymph node involvement* and who are to receive neoadjuvant hormonal therapy and radical radiotherapy.

*Estimated using the Roach formula: %LN risk = 2/3 PSA + (10 x [Gleason score - 6])

Immediate post-operative radiotherapy after radical prostatectomy is not routinely recommended, even in men with margin-positive disease, other than in the context of a clinical trial.

High-intensity focused ultrasound and cryotherapy are not recommended for men with locally advanced prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions.*

*NICE interventional procedures guidance 118, 119 and 145 evaluated the safety and efficacy of cryotherapy and high-intensity focused ultrasound for the treatment of prostate cancer. NICE clinical guidelines provide guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS. As there was a lack of evidence on quality of life benefits and long-term survival these interventions are not recommended in this guideline.

Metastatic Prostate Cancer

Hormonal Therapy

Healthcare professionals should offer bilateral orchidectomy to all men with metastatic prostate cancer as an alternative to continuous LHRHa therapy.

Combined androgen blockade is not recommended as a first-line treatment for men with metastatic prostate cancer.

For men with metastatic prostate cancer who are willing to accept the adverse impact on overall survival and gynaecomastia in the hope of retaining sexual function, anti-androgen monotherapy with bicalutamide (150 mg)* should be offered.

*At the time of publication (February 2008) bicalutamide did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

Healthcare professionals should begin androgen withdrawal and stop bicalutamide treatment in men with metastatic prostate cancer who are taking bicalutamide monotherapy and who do not maintain satisfactory sexual function.

Intermittent androgen withdrawal may be offered to men with metastatic prostate cancer providing they are informed that there is no long-term evidence of its effectiveness.

Managing the Complications of Hormonal Therapy

Synthetic progestogens (administered orally or parenterally) are recommended as first-line therapy for the management of troublesome hot flushes. If oral therapy is used, it should be given for 2 weeks, and re-started, if effective, on recurrence of symptoms.

Men starting long-term bicalutamide monotherapy (>6 months) should receive prophylactic radiotherapy to both breast buds within the first month of treatment. A single fraction of 8 Gy using orthovoltage or electron beam radiotherapy is recommended.

If radiotherapy is unsuccessful in preventing gynecomastia, weekly tamoxifen should be considered.

Inform men starting androgen withdrawal therapy that regular resistance exercise reduces fatigue and improves quality of life.

Hormone-Refractory Prostate Cancer

When men with prostate cancer develop biochemical evidence of hormone-refractory disease, their treatment options should be discussed by the urological cancer MDT with a view to seeking an oncologist and/or specialist palliative care opinion, as appropriate.

Docetaxel is recommended, within its licensed indications, as a treatment option for men with hormone-refractory prostate cancer only if their Karnofsky performance-status score is 60% or more.*

*These recommendations are from 'Docetaxel for the treatment of hormone-refractory metastatic prostate cancer' (See the NGC summary of the NICE guideline Docetaxel for the treatment of hormone-refractory metastatic prostate cancer.)

It is recommended that treatment with docetaxel should be stopped:

- At the completion of planned treatment of up to 10 cycles
- If severe adverse events occur
- In the presence of progression of disease as evidenced by clinical or laboratory criteria, or by imaging studies*

*These recommendations are from 'Docetaxel for the treatment of hormone-refractory metastatic prostate cancer' (NICE technology appraisal guidance 101). (See the NGC summary of the NICE guideline Docetaxel for the treatment of hormone-refractory metastatic prostate cancer.)

Repeat cycles of treatment with docetaxel are not recommended if the disease recurs after completion of the planned course of chemotherapy*.

*These recommendations are from 'Docetaxel for the treatment of hormone-refractory metastatic prostate cancer' (NICE technology appraisal guidance 101) (See the NGC summary of the NICE guideline Docetaxel for the treatment of hormone-refractory metastatic prostate cancer.)

A corticosteroid such as dexamethasone (0.5 mg daily) is recommended as third-line hormonal therapy after androgen withdrawal and anti-androgen therapy for men with hormone-refractory prostate cancer.

Men with hormone-refractory prostate cancer shown to have extensive metastases in the spine (for example, on a bone scan), should have spinal MRI if they develop any spinal-related symptoms.

The routine use of spinal MRI for all men with hormone-refractory prostate cancer and known bone metastases is not recommended.

The use of bisphosphonates to prevent or reduce the complications of bone metastases in men with hormone-refractory prostate cancer is not recommended.

Bisphosphonates for pain relief may be considered for men with hormone-refractory prostate cancer when other treatments (including analgesics and palliative radiotherapy) have failed. The oral or intravenous route of administration should be chosen according to convenience, tolerability and cost.

Bisphosphonates should not be used routinely to prevent osteoporosis in men with prostate cancer receiving androgen withdrawal therapy.

Strontium-89 should be considered for men with hormone-refractory prostate cancer and painful bone metastases, especially those men who are unlikely to receive myelosuppressive chemotherapy.

Decompression of the upper urinary tract by percutaneous nephrostomy or by insertion of a double J stent should be offered to men with obstructive uropathy secondary to hormone-refractory prostate cancer.

The option of no intervention should also be discussed with men with obstructive uropathy secondary to hormone-refractory prostate cancer and remains a choice for some.

Palliative Care

Men with metastatic prostate cancer should be offered tailored information and access to specialist urology and palliative care teams to address the specific needs of men with metastatic prostate cancer. They should have the opportunity to discuss any significant changes in their disease status or symptoms as these occur.

The regular assessment of needs should be applied systematically to men with metastatic prostate cancer (see 'Improving supportive and palliative care for adults with cancer' [NICE cancer service guidance 2004]).

Palliative interventions at any stage should be integrated into coordinated care, and any transitions between care settings should be facilitated as smoothly as possible.

Healthcare professionals should discuss personal preferences for palliative care as early as possible with men with metastatic prostate cancer, their partners and carers. Treatment/care plans should be tailored accordingly and the preferred place of care should be identified.

Healthcare professionals should ensure that palliative care is available when needed and is not limited to the end of life. It should not be restricted to being associated with hospice care.

CLINICAL ALGORITHM(S)

The following clinical algorithms are provided in the original guideline document:

- Prostate cancer pathway
- Diagnosis and staging
- Localized disease
- Locally advanced disease
- Follow-up and relapse after radical treatment
- Metastatic disease
- Management of complications and side effects of treatment

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on clinical and cost effectiveness evidence, and where this is insufficient, the Guideline Development Group (GDG) used all available information sources and experience to make consensus recommendations using nominal group technique.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective diagnosis, treatment, and management of prostate cancer in men

POTENTIAL HARMS

Treatment of prostate cancer may be associated with a wide range of significant adverse effects, including rectal problems after radiotherapy, sexual dysfunction, and urinary incontinence. Refer to the full version of the original guideline document for further details on management of these adverse effects.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.
- The Guideline Development Group (GDG) assumes that healthcare professionals will use clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply these guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioner in light of individual patient circumstances, the wishes of the patient and clinical expertise. The National Collaborating Centre for Cancer disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Healthcare Commission assesses the performance of National Health Service (NHS) organizations in meeting core and developmental standards set by the Department of Health in 'Standards for better health', (available from http://www.doh.gov.uk). Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organizations are planning and delivering care.

NICE has developed tools to help organizations implement this guidance (listed below). These are available on their website (ttp://guidance.nice.org.uk/CG58).

- Slides highlighting key messages for local discussion
- Costing tools:
    - Costing report to estimate the national savings and costs associated with implementation
    - Costing template to estimate the local costs and savings involved
- Implementation advice on how to put the guidance into practice and national initiatives that support this locally
- Audit support for monitoring local practice

Key Priorities for Implementation

- Healthcare professionals should adequately inform men with prostate cancer and their partners or carers about the effects of prostate cancer and the

treatment options on their sexual function, physical appearance, continence and other aspects of masculinity. Healthcare professionals should support men and their partners or carers in making treatment decisions, taking into account the effects on quality of life as well as survival.

- To help men decide whether to have a prostate biopsy, healthcare professionals should discuss with them their prostate specific antigen (PSA) level, digital rectal examination (DRE) findings (including an estimate of prostate size) and comorbidities, together with their risk factors (including increasing age and black African or black Caribbean ethnicity) and any history of a previous negative prostate biopsy. The serum PSA level alone should not automatically lead to a prostate biopsy.
- Men with low-risk localised prostate cancer who are considered suitable for radical treatment should first be offered active surveillance.
- Men undergoing radical external beam radiotherapy for localised prostate cancer (this may also apply to some men with locally advanced prostate cancer) should receive a minimum dose of 74 Gy to the prostate at no more than 2 Gy per fraction.
- Healthcare professionals should ensure that men and their partners have early and ongoing access to specialist erectile dysfunction services.
- Healthcare professionals should ensure that men with troublesome urinary symptoms after treatment have access to specialist continence services for assessment, diagnosis and conservative treatment. This may include coping strategies, along with pelvic floor muscle re-education, bladder retraining and pharmacotherapy.
- Healthcare professionals should refer men with intractable stress incontinence to a specialist surgeon for consideration of an artificial urinary sphincter.
- Biochemical relapse (a rising PSA) alone should not necessarily prompt an immediate change in treatment.
- Hormonal therapy is not routinely recommended for men with prostate cancer who have a biochemical relapse unless they have:
    - Symptomatic local disease progression
    - Any proven metastases
    - A PSA doubling time <3 months
- When men with prostate cancer develop biochemical evidence of hormone-refractory disease, their treatment options should be discussed by the urological cancer multidisciplinary team (MDT) with a view to seeking an oncologist and/or specialist palliative care opinion, as appropriate.
- Healthcare professionals should ensure that palliative care is available when needed and is not limited to the end of life. It should not be restricted to being associated with hospice care.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Cancer. Prostate cancer: diagnosis and treatment. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 38 p. (NICE clinical guideline; no. 58).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Feb

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Cancer - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Group Members: Professor Mark Baker (*Chair*) The Lead Cancer Clinician, The Leeds Teaching Hospitals; Dr John Graham (Lead clinician) Consultant Lead Clinical Oncologist, Taunton and Somerset NHS Trust; Philip Barnard, Patient/Carer Representative, Honorary Secretary, PSA Prostate Cancer Support

Association; Angela Billington, Specialist Nurse, Director of Continence Services, Bournemouth and Poole PCT; Dr Brendan Carey, Consultant Radiologist, Cookridge Hospital, Leeds; Mr David Gillatt, Consultant Urologist, Southmead Hospital, Bristol; Jane Gosling, Consultant Nurse – Urology, Derriford Hospital, Plymouth; Dr Chris Hiley, Patient/Carer Representative, Head of Policy and Research Management, The Prostate Cancer Charity; Margaret Jewitt, Superintendent Radiographer, Weston Park Hospital, Sheffield; Mr John McLoughlin, Consultant Urologist, West Suffolk Hospital Bury Edmunds and Honorary Consultant Urologist, Addenbrooke's Hospital Cambridge; Dr Chris Parker, Consultant in Clinical Oncology, Institute of Cancer Research and Royal Marsden NHS Foundation Trust, Sutton; John Rawlinson, Patient/Carer Representative, Senior Lecturer/Academic Lead in Mental Health, University of Plymouth; Professor David Weller, Head, General Practice, University of Edinburgh Primary Care; Dr John Wiles, Consultant in Palliative Medicine, Bromley Hospitals NHS Trust

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

At the start of the guideline development process all Guideline Development Group (GDG) members' interests were recorded on a standard declaration form that covered consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared new, arising conflicts of interest, which were always recorded. See Appendix 8.1 of the full version of the guideline for a list of these declarations.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Prostate cancer: diagnosis and treatment. Full guideline. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 146 p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Prostate cancer. Diagnosis and treatment. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. 12 p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Prostate cancer: diagnosis and treatment. Costing report. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. 33 p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

- Prostate cancer: diagnosis and treatment. Costing template. Implementing NICE guidance. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. Various p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Prostate cancer. Implementing NICE guidance. Slide set. London (UK): National Institute for Health and Clinical Excellence; 2008. 18 p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Prostate cancer. Audit support. London (UK): National Institute for Health and Clinical Excellence; 2008 May. 10 p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- The guidelines manual 2007. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 April. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1457. 11 Strand, London, WC2N 5HR.

Additional accompanying guideline materials can be found from the National Institute for Health and Clinical Excellence (NICE) Web site.

PATIENT RESOURCES

The following is available:

- Prostate cancer. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence; 2008 Feb. 8 p. (Clinical guideline; no. 58). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1458. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI Institute on September 22, 2009.

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